EXHIBIT #6

510(K) SUMMARY

1. Submitted By:

AUG 1 8 2009

Natalya Valerio
Air Techniques, Inc.
1295 Walt Whitman Road
Melville, NY 11747
Tel: (516) 433-7676

Date Submitted: 08/05/09

2. Device Names:

Trade/Proprietary Name: Spectra Fluorescence Caries Detection Aid System

Common Name: Spectra Caries Detection Aid

Classification: Class II, 21 CFR 872.1745

Product Code: NBL

3. Predicate Device Information:

Inspektor Pro 510(k)# K040063
Inspector Dental Care, Amsterdam, Netherlands

4. Device Description:

The Spectra Fluorescence Caries Detection Aid System aids in the diagnosis of caries. It consists of a toothbrush-sized handpiece for examining the condition of a tooth, an umbilical cord connecting the handpiece to a computer and imaging software.

5. Indications for Use:

The Spectra Fluorescence Caries Detection Aid System is indicated as an aid in the detection and diagnosis of dental caries.

6. **Discussion of Clinical Tests Performed:**

Clinical testing was performed and established the effectiveness of the device to its claims.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

The information in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to the predicate devices already in commercial distribution.

8. **Conclusions**:

Based on the same intended use and similar technological characteristics, Spectra Fluorescence Caries Detection Aid System is substantially equivalent to its predicate device Inspektor Pro cleared under 510(k) # K040063.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

AUG 1 8 2009

Air Techniques, Incorporated
Ms. Natalya Valerio
Official Correspondent
MDI Consulting, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K090169
Trade/Device Name: Spectra Fluorescence Caries Detection Aid System
Regulation Number: 872.1745
Regulation Name: Laser Fluorescence Caries Detection Device
Regulatory Class: II
Product Code: NBL
Dated: August 5, 2009
Received: August 6, 2009

Dear Ms. Valerio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

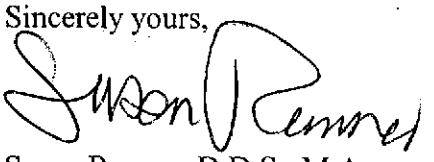
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infusion Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090169

EXHIBIT #5

Indications for Use

510(k) Number (if known): K090169

Device Name: Spectra Fluorescence Caries Detection Aid System

Indications For Use:

Spectra Fluorescence Caries Detection Aid System is indicated as an aid in the detection and diagnosis of dental caries.

Prescription Use X
(Per 21 CFR 801 Subpart D)

OR

Over-The Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090169